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EXAMINER				
BITAR, NANCY				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/577,359

**Applicant(s)**

GREGORY ET AL.

**Examiner**

NANCY BITAR

**Art Unit**

2624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-18 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-893)  
Paper No(s)/Mail Date 8/17/06, 9/20/06, 9/24/07  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Examiner Notes**

1. Examiner cites particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that, in preparing responses, the applicant fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows:

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

4. Claim(s) 4 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 4 defines a "Active Shape Model" wherein paragraph [0036] teaches as been a computer program embodying functional descriptive material. However, the claim does not define a computer-readable medium or memory and is thus non-statutory for that reason (i.e., "When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized" – Guidelines Annex IV). That is, the scope of the presently

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claimed “Active Shape Model” can range from paper on which the program is written, to a program simply contemplated and memorized by a person. The examiner suggests amending the claim to embody the program on “computer-readable medium” or equivalent in order to make the claim statutory. Any amendment to the claim should be commensurate with its corresponding disclosure.

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-5; 12-18 are rejected under 35 U.S.C. 103(a) as being anticipated by Mazess et al ( WO 94/06351) in view of Gregory et al ( Hip fractures, morphometry and geometry, April 2002)

As to claim 1, Mazess et al teaches an apparatus for predicting bone fracture risk in an osteoporotic patient (figure 1), which apparatus comprises

a Dual X-ray Absorptiometry scanner for scanning a body area of the patient and producing a Dual X-ray Absorptiometry image of the body area (dual energy x-ray densitometers to permit measurement of bone density; page 8, lines 5-15);

image analysis means for analyzing pre-determined aspects of the Dual X-ray Absorptiometry image, the aspects being pre-determined according to the part of the body being scanned, and for generating an image data set from the Dual X-ray Absorptiometry image (computer is programmed to use the data regarding shape and size to formulate indicia of vertebral condition

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having clinical and diagnostic value and then to visually display the indicia ; page 24 , lines 7-29); and data comparison means comprising a database of comparative data sets from Dual X-ray Absorptiometry images of control subjects, for comparison with the image data set for the Dual X-ray Absorptiometry image of the patient ( page 32 , lines 28-31), to thereby predict the risk of bone fracture in the patient (page 30, line 20 to page 31, line 4). While Mazess meets a number of the limitations of the claimed invention, as pointed out more fully above, Mazess fails to specifically teach the comparison means comprising a database of comparative data sets from Dual X-ray Absorptiometry images of control subjects, for comparison with the image data set for the Dual X-ray Absorptiometry image of the patient. Specifically, Gregory et al. teaches the Active shape modeling (ASM) is an image processing technique that can be used to build model of a shape. Shapes that have common features but are subject to natural variation. Moreover, Gregory teaches discriminating analysis 9 note that in the specs the comparison analysis id done with discriminant analysis) that is applied to find out which variable or combination of variables was best able to discriminate between the two groups. Using a single variable ASM (77% correct) was more accurate than 4 out of 5 of the BMD measurements, thus the classification improves. it would have been obvious to one of ordinary skill in the art to use the discrimination analysis in the Dual X-ray absorption scanner in order to predict more accurately the bone fracture risk when acquiring the DXA images. Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

The limitation of claim 18 has been addressed in claim 1.

The limitation of claim 2-5 and 14, Gregory et al teaches these limitations in the abstract, first two paragraphs.

As to claim 12- 13, Mazess teaches predicting fracture risk in different body parts wherein the predicting fracture risk in more than one of the proximal femur, wrist, ankle, hand and spine ( see figure 2; pages 13-14).

The limitation of claims 15-17 has been addressed above.

7. Claims 6--11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al, in view of Gregory et al and further in view of Giger et al ( US 5,931,780)

While Mazess meets a number of the limitations of the claimed invention, as pointed out more fully above, Mazess fails to specifically teach the image analysis means analyses the Dual X-ray Absorptiometry image by analysis of the texture of the body part and the analysis of the texture of the body part uses Fourier transforms and Principal Component Analysis. Specifically, Giger et al. teaches extracting the characteristics of the bone trabeculae using texture analysis of image data from digital images of bony parts of the body such as the spine. Moreover, Giger teaches the image data in the ROI are then input to a Fast Fourier Transform (step 50) and the power spectrum is calculated (step 60) and various textures measures are calculated from the power spectrum data (step 70) and these are merged using an artificial neural network (step 80) to yield a likelihood of risk of future fracture (step 80). Other texture analyses can be used such as fractal analysis (see figure 1; column 4, lines 1-20). In addition, Giger et al clearly teaches the measurement of both bone density (bone mass) and bone structure from a single-projection, dual-energy radiographic image of some bony body part such as the spine, hip, or extremities according to the invention. Such a system produces a high-



energy image and a low-energy from either a "one shot" exposure technique that employs two detectors sandwich together or a "two-exposure" technique that utilizes two exposures to the patient (figure 21; column 7, lines 35-43) it would have been obvious to one of ordinary skill in the art to use different prediction methods in order improves prediction quality. Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

### **Conclusion**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY BITAR whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jinge Wu can be reached on 571-272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jingge Wu/  
Supervisory Patent Examiner, Art Unit 2624

Nancy Bitar

12/17/2008